PSEUDO ANEURYSM REPAIR SYSTEM

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/409,806, filed September 10, 2002.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to medical devices and more particularly to devices and methods for accessing and draining a pseudo aneurysm and sealing the related blood vessel.

Description of the Related Art

A pseudo aneurysm may form whenever a break in a vessel allows blood to leak out of circulation into an area surrounding the blood vessel. Typically, the break is a small hole in an artery, and it may be caused by trauma or infection. Many medical therapeutic and diagnostic procedures involve the percutaneous introduction of instrumentation into a vein or artery. In each of those procedures, the closing and subsequent healing of the resultant vascular puncture is critical to the successful completion of the procedure. Not infrequently, the vascular puncture becomes infected or simply fails to properly heal. Several days after the procedure, the patient will have the severe pain and swelling associated with a pseudo aneurysm.

When a pseudo aneurysm forms, blood and other fluids pool up within the adjacent fibrous tissue and other structures surrounding the vessel. The pseudo aneurysm thus subjects the surrounding anatomy to increased pressure causing severe pain and often tissue damage. In addition, draining the pseudo aneurysm and sealing the vessel may be a risky or difficult procedure depending on the location of the pseudo aneurysm and the overlying and surrounding anatomy.

The prior art includes devices for closing an opening in a vessel when completing a surgical procedure. These devices, however, enter the vessel through the opening that needs

to be closed. Because procedures using these devices are often performed during the underlying surgery, many of these devices rely upon the guide wires or catheters that were used in the primary surgical procedure still in place. These devices are designed to seal the vessel prior to the formation of a pseudo aneurysm. Thus, they do not address the problem of treating a pseudo aneurysm after it has formed. There exists a need for a device and method designed for sealing a vessel at any point after surgery, even days later when a painful pseudo aneurysm has formed. Furthermore, a need exists for a device and method designed for accessing and draining a pseudo aneurysm.

SUMMARY OF THE INVENTION

The present invention addresses some if not all of these needs. The method of this invention can be used to drain a pseudo aneurysm and to seal a puncture in a blood vessel. In one application, the method comprises inserting an introducer needle percutaneously directly into a pseudo aneurysm sack, and then inserting a guide wire through the needle and into the pseudo aneurysm sack. The practitioner next removes the needle while leaving the guide wire in place. The method further comprises advancing a multi-lumen catheter along the guide wire and into the pseudo aneurysm sack by feeding the guide wire through a lumen of the catheter or a slot or groove in the catheter. In one application, the practitioner may use the catheter to inject contrast media into the pseudo aneurysm sack. The practitioner then advances the guide wire through the related puncture in the blood vessel and advances the catheter along the guide wire and through the puncture. The practitioner then inflates one or more balloons attached to the distal end of the catheter to occlude the puncture in the blood vessel and inhibit blood and other fluids from flowing between the blood vessel and the pseudo aneurysm. The method further comprises aspirating the pseudo aneurysm sack and injecting a coagulant to help clot the vessel puncture. Lastly, the practitioner deflates the one or more balloons and removes the balloon(s), catheter, and guide wire.

In an alternative application, the inventive method comprises treating the pseudo aneurysm through the vasculature whereby an introducer needle is inserted into the vasculature and a guidewire is inserted therethrough. The guidewire is then directed through the vasculature to the site adjacent the pseudo aneurysm and through the opening in the vessel wall to the pseudo aneurysm.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates one application of the present invention and more specifically illustrates the step of removing the needle.

Figure 2 illustrates one application of the present invention and more specifically illustrates the catheter system in place with the balloons inflated to occlude a puncture in a blood vessel.

Figure 3 illustrates a perspective view of one embodiment of the catheter system designed for use with applications of the present invention.

Figure 4 illustrates an exploded view of one embodiment of a catheter system designed for use with applications of the present invention.

Figure 5 illustrates an exploded view of an alternate embodiment of a catheter system designed for use with applications of the present invention.

Figure 6 illustrates another application of the present invention and more specifically illustrates the step of advancing a catheter over a guide wire.

Figure 7 further illustrates another application of the present invention and more specifically the step of advancing a catheter over a guide wire.

Figure 8 illustrates an embodiment of a catheter system with a catheter comprising a shaped shaft profile designed for use with applications of the present invention.

Figure 9 illustrates an embodiment of a catheter system with a catheter having balloons comprising a shaped profile designed for use with applications of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to **Figures 1 and 2,** one application of the present invention comprises a method for draining a pseudo aneurysm **10** and sealing a related puncture **12** in a blood vessel **14**. In this application, a practitioner inserts a needle **16** into the pseudo aneurysm sack **10**. The practitioner can verify the location of the needle **16** in the pseudo aneurysm sack **10** by checking for red blood flow at the back of the needle **16**. The method then comprises inserting a guide wire **18** through the needle **16** and into the pseudo aneurysm sack **10**. In certain preferred embodiments, the guide wire **18** is about .01 inches, more preferably about .014 inches. The method further comprises removing the needle **16** while leaving the guide

wire **18** in place. Next, the practitioner uses the guide wire **18** to insert a multi-lumen catheter system **20** designed for use with this application.

Referring to **Figures 3 and 4**, a multi-lumen catheter system **20** designed for use with this application of the present invention comprises a multi-lumen catheter **24** incorporating one lumen for a guide wire **28**, one balloon inflation/deflation lumen **30**, and one lumen for the withdrawal and infusion of fluids **32**. The distal end **34** of the multi-lumen catheter **24** is preferably tapered to provide easier insertion through the skin. A balloon **36** is secured to the distal end **34** of the catheter **24.** Proximate the balloon **36**, either proximally or distally, the fluid lumen **32** includes one or more holes or slots **40**. In one embodiment, the holes **40** are oval in shape along the longitudinal length of the catheter **24**.

In the embodiment of **Figure 4,** the three lumens are separate from each other. In an alternative embodiment, the lumens could be arranged coaxially. In addition, any of the three lumens can be designed for use as a guide wire lumen **28**, a balloon inflation lumen **30**, or a fluid lumen **32**. The spatial relationship of the three lumens can vary. In an alternate embodiment shown in **Figure 5**, the catheter **24** comprises a groove or slot **29** rather than a lumen for advancing the catheter **24** along the guide wire **18**.

As shown in **Figure 3**, the proximal end of the catheter **44** can include a tapered or twist Luer type fitting **46** connected to the balloon inflation/deflation lumen **30**. The same type of fitting **46** can also be used for the proximal terminations of the guide wire lumen **28** and the fluid lumen **32**. As shown in **Figure 3**, these terminations may be incorporated into a single handle or yoke piece **48**. In other embodiments, the terminations may have multiple individual ends. It will also be appreciated that any available fitting could be substituted for the Luer type fitting.

In some embodiments of the catheter system **20**, the balloon **36** is a "T" or low profile disk shaped balloon. When this type of balloon is inflated to block an opening in a vessel, the top of the "T" or the disk can rest against the inside of the target vessel wall. Other embodiments of the catheter system may comprise more than one balloon, and the balloon(s) may have various different geometries including, for example, an hourglass or a peanut shape as illustrated in **Figure 3**. An hourglass shaped balloon rests partially inside of the target vessel and partially outside of the target vessel. Other embodiments of the catheter system **20**

include one or more tube balloons formed using a length of compliant material. With tube balloons, no secondary balloon forming or molding is required.

The balloon material can be compliant or non-compliant. In some embodiments, the balloon **36** may comprise one or more of the following compliant materials: polyethylene, polyurethane, or Tecoflex®. In some embodiments, the balloon may also comprise one or more of the following non-compliant materials: nylon, polyester (e.g. PET - polyethylene terephthalate), Pebax®, or polymide. The balloon may be fabricated using any suitable method or process including but not limited to molding, extrusion, heat forming, or cold forming. In addition, the balloon may be bonded to the catheter using any suitable method or process including, but not limited to, thermal, laser, adhesive, solvent, ultrasonic welding, or molding.

The tubular body **52** of the catheter **24** can be fabricated from any medical grade polymer such as nylon, polyethylene, Pebax®, polymide, polyester, polypropylene, and/or any combination of these or other suitable materials. In some embodiments, the shaft of the tubular body **52** can be reinforced using a polymer, a metal, a metal alloy (e.g., nitinol, stainless steel, Elgiloy®, iconel, 17-7PH®), and/or any combination of these or other suitable materials. In other embodiments, the shaft can be further reinforced, or separately reinforced, using a reinforcing component or technique including but not limited to the following: one or more wires having a round, flat, or any other cross sectional shape; multiple tubing layers, with or without a tie, or bonding layer; a mandrel; a hypo tube; irradiation; variable wall thickness; and/or any combination of these or other suitable reinforcing components and techniques. The reinforcing components can be either removable or fixed. In addition, the reinforcement can be along the entire length, or along a partial length at selected locations, and can be used to improve catheter trackability and pushability. The reinforcement can also provide a strain relief transition between bonded catheter segments. In some embodiments, the distal section of the tubular body **52** of the catheter **24** can be fabricated from a softer, more atraumatic material. The two or more sections may be joined together using heat and or adhesives or any other suitable process or method.

Methods of forming tubular bodies are known in the prior art. The tubular body **52** of the catheter **24** can be formed using any of the known methods of fabricating tubular bodies

such as: single or multiple layer extrusion, casting, injection molding, dip coating, or any other suitable fabrication process or method. The tubular body **30** can also be reinforced by using a coil, braid, wrap, or any other suitable reinforcement. The holes or grooves used for fluid extraction or infusion ports **20** may be created by laser, drill sharpened mandrel, or any other suitable method or combination of methods.

The yoke piece **48** can be produced from polycarbonate, or another suitable material, using machining, casting, injection molding, or any other suitable process. In some embodiments, the yoke piece may contain interior grooves or channels to allow the catheter lumens to be joined or connected to the corresponding proximal tubes, providing fluid and air tight passages for each of the device lumens. During assembly, the two halves of the yoke piece can be bonded together using mechanical press fit, adhesives, solvents, sonic welding, or any other suitable method or process.

In one application of the present invention, the method comprises the step of advancing the guide wire **18** through the guide wire lumen of the catheter **28** until the holes **40** in the catheter **24** are inside of the pseudo aneurysm sack **10**. It is contemplated that at least one way to load the guide wire is described in co-pending application No. 10/272,209, entitled "Guide Wire Insertion Tool," which is incorporated herein by reference.

The method further comprises injecting contrast media that allows visualization of the pseudo aneurysm sack **10** and the location of the vessel puncture **12**. In certain preferred applications, the contrast media is an ionic or non-ionic liquid contrast agent that can be visualized using a fluoroscope. Using the visualization, the practitioner then advances the guide wire **18** through the vessel puncture **12** and into the vessel **14**.

Once the guide wire **18** is inside the vessel **14**, the method further comprises advancing the catheter **24** along the guide wire **18** and through the vessel puncture **12**. The distal end **34** of the catheter **24** should be far enough inside of the vessel **14** that the one or more balloons **36** can be inflated to occlude the vessel puncture as illustrated in **Figure 4**. The method then comprises using the balloon inflation lumen **30** to inflate the one or more balloons **36** thereby isolating the vessel **14** from the pseudo aneurysm sack **10**. In one application, the balloon(s) **36** can occlude the puncture from inside of the vessel **14.** In other applications, a balloon **36** may be tapered in the middle so that half of the balloon occludes

the puncture from inside the vessel **14** while the other half of the balloon occludes the puncture from outside of the vessel **14**. Similarly in some applications with more than one balloon **36**, one or more balloons may occlude the puncture from inside the vessel **14** while one or more balloons also occlude the pressure from outside the vessel **14**. In still other applications, the balloon **36** may occlude the puncture only from outside the vessel **14**.

The method further comprises using a syringe to aspirate the pseudo aneurysm sack **10** through the fluid lumen **32** of the catheter **24**. In some applications, the practitioner may then use the fluid lumen **32** to inject a coagulant such as thrombin to help clot the puncture **12** in the vessel **14**. The method then comprises deflating the one or more balloons **36** and slowly withdrawing the catheter **24** and the wire **18**. Manual compression can help to stop any remaining bleeding.

In another application of the present invention, shown in **Figures 6 and 7,** the method comprises accessing the pseudo aneurysm **10** from the vessel **14** rather than going through the anatomy surrounding the vessel **58**. This application allows the practitioner to access the pseudo aneurysm **10** without disturbing the surrounding anatomy **58**. In many cases, accessing the pseudo aneurysm **10** through the surrounding anatomy **58** can be a difficult, high risk, or painful procedure.

In this application, the method comprises inserting a needle **16** into a blood vessel **14** rather than into the pseudo aneurysm **10**. As described above with respect to the first application, the method comprises inserting a guide wire **18** through the needle **16** and removing the needle **16** while leaving the guide wire **18** in place. The method next comprises advancing the catheter **24** into the vessel **14**. Once the catheter **24** is inside of the vessel **14**, the method comprises injecting a contrast media similar to the contrast media discussed above with regard to other applications. Using the contrast media to visualize the vessel **14**, the practitioner advances the guide wire **18** along the vessel **14** to the location of the vessel puncture **12**. The method further comprises advancing the guide wire **18** through the vessel puncture **12**, and into the pseudo aneurysm sack **10**. The method then comprises advancing the catheter **24** along the guide wire **18** such that the distal end **34** of the catheter **24** enters the pseudo aneurysm **10**.

In this application, the method next comprises inflating the one or more balloons **36** using the balloon inflation lumen **30**. The balloon(s) **36** occlude the vessel puncture **12** as discussed above. After inflating the balloon(s) **36** and occluding the vessel puncture **12**, the practitioner drains the pseudo aneurysm sack **10** and seals the vessel puncture **12** as described above.

Although the application shown in **Figure 6** comprises approaching the pseudo aneurysm **10** through the femoral artery from the contra lateral side, other embodiments of the present invention comprise different approaches. For example, in other embodiments the practitioner may start in one artery and cross over to the relevant artery, or the practitioner may start in a vein and cross over to the relevant artery using a shunt. In addition, various embodiments of the present invention comprise starting at a point distal to the pseudo aneurysm **10** and heading proximally as well as starting at a point proximal to the pseudo aneurysm **10** and heading distally.

In yet another application of the present invention, the catheter system **20**, as shown in **Figure 8**, comprises a catheter **24** with an hourglass or peanut shaped shaft profile **60**. This catheter system does not require a balloon **36**; however, it may comprise one or more balloons. A practitioner can use this catheter system **20** with any of the applications described above. The practitioner can insert the catheter **24** directly percutaneously into the pseudo aneurysm **10**, or the practitioner can insert the catheter into a blood vessel **14** and follow the vessel **14** into the pseudo aneurysm **10** as described above. The hourglass or peanut shaped shaft profile **60** can provide the practitioner with feedback as to the location of the distal end of the catheter **34** relative to the vessel puncture **12**. The feedback comprises an increased resistance felt when pushing the larger diameter portions of the shaft through the puncture **12** and a decreased resistance felt when pushing the smaller diameter portion through the puncture. In an alternate application, a catheter **24** without an hourglass or peanut shaped profile can be used with an hourglass or peanut shaped balloon **36** near the distal end of the catheter **34**. The practitioner can inflate the balloon **36** before inserting the catheter **24** through the vessel puncture **12**. This can similarly provide the practitioner with feedback as to the location of the catheter **34** relative to the vessel puncture **12**. Alternately two adjacent balloons **36** can provide the same effect as shown in **Figure 9**.

In another application of the present invention, the catheter system **20** does not require a balloon **36** or an hourglass or peanut shaped shaft profile **60**. In this application, the practitioner need not utilize a balloon **36** or a shaped shaft **60** to obstruct the vessel puncture **12**. Instead, the method comprises injecting a material that is too viscous to easily seep into the vessel **14** through the puncture site **12**. One such material is thixotropic fluid, but other materials may be used as well.